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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,618	03/01/2004	Antonius Franciscus Wilhelmus van der Steen	2183-6375US	8842

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TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,618	VAN DER STEEN ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 and 10-24 is/are rejected.

7)☒ Claim(s) 9 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the Netherlands on August 31, 2001. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Torp et al (6,099,471).

Torp et al disclose a means for real-time calculation and display of strain and further disclose receiving signals from a tissue with a sensor for measuring the deformation of the tissue in a measuring plane defined by the sensor, which sensor, during a varying pressure exerted on the tissue, is moved along the tissue in a direction transverse to the measuring plane; identifying strain of the tissue from the resulting signals; relating the strain to elasticity, hardness or hardness and elasticity parameters of the tissue; correlating signals consecutive over time, which signals are representative of the deformation of the tissue in case of positions of the sensor mutually moved with respect to each other; and calculating, by means of said correlation, strain in a tissue surface or

tissue volume part extending practically parallel to the direction of motion of the sensor; displaying elasticity and/or hardness parameters of a tissue surface or tissue volume part; the signals are echographic data detected with an acoustic sensor; displaying elasticity and/or hardness parameters of the tissue with position information of the sensor and/or the tissue; the signals are received during practically continuous motion of the sensor; and signals possessing an overlap are received. See Column 5, lines 11-34; Column 6, lines 14-17; Column 7, lines 54-61; and Column 8, lines 8-17.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 5 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) as applied to claim 1 above, and further in view of Panescu et al (5,848,969).

Torp et al, as discussed above, disclose a means of measuring tissue strain, but fail to disclose the signals are optical data detected with an optical sensor; signals, at an assumed cyclic pressure change, are received at predetermined time intervals in the period of the motion; the signals come from a blood vessel wall and the data are received only during a specific time interval of the period of the heartbeat; and the tissue is an artery moving through the heartbeat in the longitudinal direction, and the sensor is

moved practically parallel to this direction, so that, during at least one detection period, the sensor has a practically fixed position relative to the wall of the artery.

Panescu et al disclose a means for imaging internal structures and further disclose the signals are optical data detected with an optical sensor; signals, at an assumed cyclic pressure change, are received at predetermined time intervals in the period of the motion; the signals come from a blood vessel wall and the data are received only during a specific time interval of the period of the heartbeat; and the tissue is an artery moving through the heartbeat in the longitudinal direction, and the sensor is moved practically parallel to this direction, so that, during at least one detection period, the sensor has a practically fixed position relative to the wall of the artery. See Column 3, lines 59-67; Column 4, lines 1-5; Column 6, lines 61-65; Column 10, lines 44-67; Column 11, lines 1-12, 25-35 and 56-63; and Column 17, lines 21-40.

Since both Torp et al and Panescu et al disclose means for viewing internal structures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Torp et al to include the ability of using an optical sensor as well as using the device inside a blood vessel, as per the teachings of Panescu et al, since it is well known in the art to use different types of sensors to view tissue, in particularly within the vasculature.

6. Claims 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) in view of Panescu et al (5,848,969).

Torp et al, as discussed above, disclose a means of measuring tissue strain, and further disclose a processor device for collecting and processing signals from the sensor to

identify strain of the tissue and to relate the strain to elasticity and/or hardness parameters of a tissue surface or tissue volume part; a display device for displaying elasticity and/or hardness parameters of the tissue surface or tissue volume part; correlation detection means for detecting the correlation between consecutive signals, which signals are representative of the deformation of the tissue in case of positions of the sensor mutually moved with respect to each other; the processor device being arranged to calculate by means of said correlation a strain in a tissue surface or tissue volume part extending practically parallel to the direction of motion of the sensor; first activating means for activating data storage means for storing signals; and the activating means are connected with the correlation detection means to become active at a predetermined correlation. See Column 5, lines 11-34; Column 6, lines 14-17; Column 7, lines 54-61; and Column 8, lines 8-17.

Torp et al however fail to disclose a sensor movable through a blood vessel or body cavity for recording signals from a tissue; a position recording means coupled with the processor device to record sensor positions; an actuator for moving the sensor; the actuator has an adjustable speed of motion; second activating means for activating the actuator; the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat; the sensor is arranged in a catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pullback of the catheter; and the sensor is an optical sensor.

Panescu et al, as discussed above, disclose means for imaging internal tissue structures and further disclose a sensor movable through a blood vessel or body cavity

for recording signals from a tissue; a position recording means coupled with the processor device to record sensor positions; an actuator for moving the sensor; the actuator has an adjustable speed of motion; second activating means for activating the actuator; the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat; the sensor is arranged in a catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pullback of the catheter; and the sensor is an optical sensor. See Column 3, lines 59-67; Column 4, lines 1-5; Column 6, lines 61-65; Column 10, lines 44-67; Column 11, lines 1-12, 25-35 and 56-63; and Column 17, lines 21-40.

Since both Torp et al and Panescu et al disclose means for viewing internal structures, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Torp et al to include the ability of using an optical sensor as well as using the device inside a blood vessel, as per the teachings of Panescu et al, since it is well known in the art to use different types of sensors to view tissue, in particularly within the vasculature.

Allowable Subject Matter

7. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art of Sarvazyan (5,785,663) and Sarvazyan et al (5,524,636) both disclose means for measuring the elasticity of tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BS

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700